

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

September 2, 2015

Brian Anson Regulatory Affairs Project Manager L. Perrigo Co. 515 Eastern Ave. Allegan, MI 49010

Subject: Notification per PRN 98-10 – adding additional label claims

Product Name: 0.5% Permethrin Aerosol Spray

EPA Registration Number: 71-1 Application Date: 7/22/2015 Decision Number: 507455

Dear Mr. Anson:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, you may contact Angela Hollis at 703-347-0216 or via email at hollis.angela@epa.gov.

Sincerely,

Jennifer Urbanski, Ph.D., Product Manager 4 Invertebrate and Vertebrate Branch 1

Registration Division (7505P) Office of Pesticide Programs

- Bedding spray [lice treatment]
- For bedding and furniture
 - OR For use on bedding
 - OR For use on bedding, furniture and other inanimate objects infested with lice
 - OR Home lice control spray [for bedding and furniture]
- Kills lice [and their eggs] on mattresses <u>OR</u> [bedding], furniture, car interiors [and] other nonwashable items
- [Spray] Kills lice, bedbugs & dust mites on bedding, mattresses, furniture and car interiors
- Kills lice [and their eggs]
- [Spray] Lice treatment [kills lice]
 OR Lice treatment- for use on bedding [& furniture]
- [Lice] [bed][[ding]] spray
- In-home [lice control spray]
 OR [In-] Home lice, [&] bedbug [& dust mite] spray
- Lice [control OR treatment]
- Shake well before using
- [Step 3:] [of] 1-2-3 lice control system

OR Stop lice step 3

OR [Step] 3 [: Spray]

OR 3 Control

OR Step 3 [clear]

OR [Step 3] Home lice, bed bug & dust mite spray

- Questions? 1-800-XXX-XXXX
 - OR Questions or comments: 1-800-XXX-XXXX
 - OR For comments or questions please call 1-800-XXX-XXXX
- Aviso al consumidor: si no sabe inglés, pídale a alguien que le lea toda la información que aparece en el empaque antes de utilizar este producto.
 - Notice to consumer: If you are unable to read English, please have someone read the full packaging label to you before using this product.
- Not for use on humans [or animals]
- Spray kills lice & bedbugs on bedding & furniture

NOTIFICATION

71-1

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

09/02/2015

- Kills bed bugs
- Controls residential and garden insects
- For treatment of clothing, nets, sleeping bags & backpacks
- Kills & repels mosquitoes and ticks
- Controls ticks that can cause lyme disease
- Repels ticks that can cause lyme disease
- One clothing [fabric] treatment lasts 2 weeks [!]
- A water based aerosol
- Controls pests for up to four weeks
- Kills house [Helps control] dust mites in carpets, curtains and on upholstery
- Controls house [Helps control] dust mites (Dermatophogoides spp.) for up to 8 weeks [2 months,
 60/days] in carpets, curtains and on upholstery
- Controls house [Helps control] dust mites that may cause asthma, hay fever, rhinitis, wateryeyes, sneezing
- For bedding and furniture this product [product name] is effective in the control of dust mites
- Kills carpet beetles
- Kills ants
- Kills: houseflies, fruit flies, mosquitoes, gnats, black flies, skipper flies, blow flies, lady bugs [beetles] and small flying moths
- Kills: cockroaches, waterbugs, palmetto bugs, silverfish, firebrats, crickets, scorpions, spiders,
 millipedes, centipedes, sowbugs and pillbugs
- Read entire label before [each] use

[[HOME] LICE, BEDBUG & DUST MITE SPRAY]

[Not for use on humans]

This product is Step 3 of a three step lice control system [that includes a shampoo as Step 1 and a combing gel as Step 2].

Step 1: Kill lice with [product name]. Re-apply in 10 days.

Step 2: Comb out eggs & nits with [insert product name]

Step 3: Clean home. Use this product [OR product name] for non-washable items.

Washables should be washed in hot water and dried in high heat.

ACTIVE INGREDIENT:

tt OTHER INGREDIENTS:.....99.50%

100.00%

tCis/trans ratio: Max. 55%(+/-) cis and Min. 45%(+/-)trans.

ttContains petroleum distillate.

KEEP OUT OF REACH OF CHILDREN CAUTION[:] See Back [Side] Panel for Additional Precautions

Aviso al consumidor: si no sabe inglés, pídale a alguien que le lea toda la información que aparece en el empaque antes de utilizar este producto.

Notice to consumer: If you are unable to read English, please have someone read the full packaging label to you before using this product.

EPA Reg. No. 71-1

EPA Est. No. See Bottom or Top of Can

FIRST AID	
If on skin	Take off contaminated clothing.
or clothing:	 Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
If in eyes:	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
[If swallowed:]	 [• Immediately call a poison control center or doctor. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give any liquid to the person.
[If inhaled:]	 Do not give anything by mouth to an unconscious person.] [Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.]
	HOT LINE NUMBER
for treatment.	duct container or label with you when calling a poison control center or doctor, or going For additional information on this product (including health concerns, medical or pesticide incidents), you may call X-XXX-XXX-XXXX.
	NOTE TO PHYSICIAN
Contains petr	oleum distillate – vomiting may cause aspiration pneumonia.

NET CONTENTS: [NET Weight: #oz. (#g)]

PRECAUTIONARY STATEMENTS Hazards to Humans & Domestic Animals

CAUTION: Harmful if absorbed through skin. [Avoid inhalation of spray mist.] Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco or the toilet. Remove and wash contaminated clothing before reuse. [Avoid contamination of feed and foodstuffs.]

[Products used exclusively indoors may omit the Environmental Hazards Statement.]

ENVIRONMENTAL HAZARDS

This product is extremely toxic to aquatic organisms, including fish and invertebrates. Do not apply directly to or near water. Drift and run-off may be hazardous to fish in water adjacent to treated areas. Do not contaminate water when disposing of equipment washwater or rinsate. See Directions for Use for additional precautions and requirements.

This pesticide is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area.

PHYSICAL OR CHEMICAL HAZARDS

Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F (54°C) may cause bursting.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Use Restrictions:

- [[Except when applying to clothing,] Do not allow adults, children, or pets to enter until
 vapors, mists and aerosols have dispersed, and the treated area has been thoroughly
 ventilated.]
- [Except when applying to clothing,] Do not allow adults, children, or pets to enter the treated area until sprays have dried.
- In the home, all food processing surfaces and utensils should be covered during treatment or thoroughly washed before use. Exposed food should be covered or removed.
- Remove pets, birds and cover any water inhabited by fish (such as aquariums and ornamental fish ponds) before application. Turn off aquarium filtering systems before spraying and wait approximately 15 minutes after application before turning the filter back on.
- This product is not for use on humans. If lice infestations should occur on humans, use a product labeled for use on humans.

- Application is prohibited directly into sewers or drains, or to any area like a gutter
 where drainage to sewers, storm drains, water bodies, or aquatic habitat can occur. Do
 not allow the product to enter any drain during or after application.
- Not for broadcast use on indoor residential surfaces.

[Products used exclusively indoors may omit the following restrictions:]

- All outdoor applications must be limited to spot or crack-and-crevice treatment only except for the following permitted uses:
 - 1. Treatment to soil or vegetation around structures
 - 2. Applications to lawns, turf and other vegetation
 - 3. Applications to building foundations up to a maximum height of 3 feet Other than applications to building foundations, all outdoor applications to impervious surfaces such as sidewalks, driveways, patios, porches and structural surfaces (such as windows, doors and eaves) are limited to spot and crack-and-crevice applications only.
- Do not water the treated area to the point of run-off.
- Don not make applications during rain.

[We recommend that those with asthma or severe allergies consult their doctor before using this product and have someone else apply this product.]

SHAKE WELL BEFORE USING

Remove protective cap. Hold container upright [with nozzle away from you.] [Depress valve] and spray from a distance of [12 to 15 inches (8 to 10 inches for clothing, furniture and bedding)] OR [8-10 inches (12 to 15 inches for baseboards, moldings and floors)]. Test product on an inconspicuous area before applying [to check for possible staining or discoloration]. [Inspect again after drying.] [Spray until surface is slightly wet, but not to the point of run-off.] OR [Spray to the point of dampness but not run-off.] Over application may cause damage. Will not stain surfaces or fabrics where water alone causes no damage.

To kill *Lice* and *Louse eggs:* Clean home. Use this product for non-washable items. Washables should be washed in hot water and dried in high heat. Spray in an inconspicuous area to test for possible staining or discoloration. Inspect again after drying, then proceed to spray entire area to be treated. Hold container upright with nozzle away from you. Depress valve and spray from a distance of 8 to 10 inches. Spray each square foot for three seconds. Spray to the point of dampness but not run-off. Allow all sprayed articles to dry thoroughly before use. If lice infestation occurs on humans, use a product labeled for use on humans. Spray only those articles and parts of bedding including mattresses and furniture that cannot be either laundered or dry-cleaned. Do not use on sheets or pillowcases.

Bedbugs: Spray mattresses, particularly around tufts and seams. Take beds apart and spray into all joints. Treat baseboards, moldings and floors. Spray to the point of dampness but not run-of. After mattress is dry, cover with mattress cover and sheet. Do not use mattress without cover. Retreat if infestation occurs, but not more than once every two weeks.

To control [Kill] [Helps Control] House Dust Mites (Dermatophagoides spp.): this product [OR product name] controls [helps control] house dust mites that may cause asthma, hay fever, rhinitis. watery eyes and sneezing. One treatment lasts for up to 8 weeks [2 months, 60 days]. On Upholstered Furniture – test fabric in an inconspicuous area to insure dyes will not bleed. [Hold container upright with nozzle away from you. Depress valve and spray from a distance of 8 to 10 inches.] Spray all fabric surfaces until damp. [Spray to the point of dampness but not run-off.] Do not use on delicate fabrics. Allow furniture to dry thoroughly before using. On Carpets-Spray over entire carpet until damp. [Spray to the point of dampness but not run-off.] Hold nozzle approximately 12 to 18 inches from the carpet surface and spray in a sweeping motion. Use an overlapping pattern to insure total coverage. After application, brush the surface of the carpet with a broom or brush to insure deep penetration. Allow carpet to dry thoroughly before reentering the treated area. Drying time can be accelerated by using a fan. On Mattresses-Spray the top, bottom and sides of mattresses until damp, paying particular attention to tufts and seams. Allow to dry thoroughly before using. After mattress is dry, cover with mattress cover and sheet. Do not use mattress without cover. Vacuum entire area once dry. Since vacuuming stirs dust up in the air those with allergies should have another person vacuum or should wear a dust mask and use vacuum with a high efficiency particulate (HEPA) filter.

Carpet Beetles: Spray directly on beetles, floors, baseboards, shelves, and carpets. Spray to the point of dampness but not run-off. Retreat if infestation occurs, but not more than once every two weeks.

Houseflies, Fruit Flies, Mosquitoes, Gnats, Black Flies, Skipper Flies, Blow Flies and Small Flying Moths: Close all doors and windows and spray room at the rate of 2 to 3 seconds per 1000 cubic feet. Direct spray to all parts of the room, especially windows and other light sources, which attract these insects. Keep nozzle in constant motion. Retreat if infestation occurs, but not more than once every two weeks.

Cockroaches, Waterbugs, Palmetto Bugs, Silverfish, Firebrats, Crickets, Scorpions, Spiders, Millipedes, Centipedes, Sowbugs and Pillbugs: Spray into hiding places such as cracks and crevices, behind sinks, cabinets, along baseboards and floors, around drains and plumbing, hitting insects with spray whenever possible. Spray to the point of dampness but not runoff. Retreat if infestation occurs, but not more than once every two weeks.

Ants: Spray trails, nests and points of entry. Spray on ants where possible. Retreat if infestation occurs, but not more than once every two weeks.

Indian Meal Moths, Angoumois Grain Moths: Close doors and windows, direct spray into all parts of room especially around stored food product containers, pallets and darkened areas. Spray 7 to 10 seconds for each 1000 cubic feet of space. Keep area closed for 15 minutes following treatment. Spray to the point of dampness but not run-off. Retreat if infestation occurs, but not more than once every two weeks.

TO CONTROL *Clothes Moths* and *Carpet Beetles:* on wool and other proteinaceous fibers: Remove infested articles from storage, brush thoroughly, and air for several hours in sunlight, if possible. Apply spray liberally to empty chests, closets, bureaus and other storages directing the spray into cracks, joints and crevices. Spray to the point of dampness but not run-off. After airing, infested articles may be treated by spraying lightly, keeping nozzle at least three feet from fabric to avoid staining.

CLOTHING TREATMENT

Clothing treatment only-do not apply to skin.

For protection against *Ticks* (including those which may carry Lyme disease) and *Mosquitoes*, apply product as directed below. For further protection, use in conjunction with an insect repellent registered for direct application to the skin and utilize the following primary preventive measures. Avoid areas where the pests are found, wear appropriate protective clothing (light-colored, long-sleeved shirt and long pants tucked into socks) and inspect body daily for ticks. Pant cuffs should be worn inside the socks or footwear to ensure full protection against ticks.

Initial Treatment Instructions:

- 1. Select a well-ventilated outdoor area protected from wind and lay out the clothing to be treated (as complete outfit; shirt, trousers and socks.)
- 2. Hold can upright about 6 to 8 inches from surface of the clothing and spray with a slow sweeping motion to lightly moisten the surface of the fabric.
- 3. Continue spraying over entire outfit, until a total treatment time of 60 seconds has elapsed and the outer surface of the fabric is moist enough to cause a slight color change or darkening. Pay special attention to socks, trouser cuffs and shirt cuffs.
- 4. Turn the clothing over and teat the other side as described in Steps 2 & 3.
- 5. Hang the treated clothing and allow to dry for at least 2 hours (4 hours under humid conditions) before wearing.
- 6. One [# oz] can will treat one [two] complete outfits(s). Do not exceed recommended spraying times.

Retreatment Instructions:

The product contains an active ingredient which actually binds to the fabric being treated, providing residual protection which lasts a minimum of two weeks, and hold up through several machine washings. DO NOT RETREAT CLOTHING MORE THAN ONCE EVERY TWO WEEKS. LAUNDER CLOTHING AT LEAST ONCE BEFORE RETREATING. For retreatment, follow instructions for initial treatment.

TREATMENT OF NETS, TENTS, SLEEPING BAGS AND BACKPACKS:

Initial Treatment Instructions: Do not treat inside of sleeping bag. Spray exterior surfaces of tent only. Select a well-ventilated outdoor area protected from wind and lay out article to be treated. Hold can upright about 6 to 8 inches from surface of the article and spray with a slow sweeping motion to lightly moisten the surface of the fabric. Continue spraying over entire article, until the outer surface of the article is moist enough to cause a light color change or darkening. Turn the article over and treat the other side as described in steps 2 and 3 above for clothing treatment. Hang the treated article and allow to dry for at least 2 hours (4 hours under humid conditions) before using.

Retreatment Instructions:

The product contains an active ingredient which actually binds to the fabric being treated, providing residual protection which lasts a minimum of two weeks, and hold up through several machine washings. DO NOT RETREAT CLOTHING MORE THAN ONCE EVERY TWO WEEKS. For retreatment, follow instructions for initial treatment.

FOR THE CONTROL OF GARDEN INSECTS: For use on roses, dahlias, asters and other ornamentals to kill *Japanese Beetles* hit by spray, as well as *Whiteflies, Aphids, Exposed Thrips, Spider Mites, Red Mites* and *Leafminers*.

May be used on plants, as well as a multi-purpose spray in small gardens and for spot treatments of incipient insect infestations to prevent spreading in large garden areas.

May also be used on other plants such as African violets, asters, azaleas, begonias, camellias, carnations, chrysanthemums, dahlias, delphiniums, dogwood, English ivy, euonymus, fuschia, geraniums, crassula, grape vine, Kentia palm, laurel, marigolds, rhododendrons, roses, rubber plants, snapdragons, stocks, wandering Jews and zinnias.

Effective when used as directed against *Whiteflies, Aphids, Spider* and *Red Mites, Exposed Thrips, Lace Bugs, Japanese Beetles, Pavement Ants, Clover Mites* and *Armyworms*. When spraying plants, do not operate closer than 18 inches. Use sweeping motion. Spray in one second bursts. Be cautious about wetting tender foliage, young plants and new growth. Do not spray plants when temperatures exceed 90°F (32°C). Over application may cause damage. Contact insects directly whenever possible. Retreat if infestation occurs, but not more than once every two weeks.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in a cool, dry area away from [inaccessible to] children and pets and away from heat, sparks and open flame. Do not transport or store below 32°F (0°C). [Protect from freezing.] [Do not freeze.]

Pesticide Disposal and Container Handling: Do Not Puncture or Incinerate.

If empty: Place in trash or offer for recycling if available.

If partly filled: Call your local solid waste agency [or 1-800-XXX-XXXX] for disposal instructions.

[Never place unused product down any indoor or outdoor drain.]

[This container may be recycled in aerosol recycling centers. At present, there are only a few such centers in the country. Before offering for recycling, empty the can by using the product according to the label.]

[NOTICE:] To the extent consistent with applicable law, purchaser assumes all responsibility for safety and use not in accordance with directions.